# Proposed Decision Memo for Intensive Cardiac Rehabilitation (ICR) Program - Pritikin Program (CAG-00418N)

## Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The Pritikin Program meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c) and, as such, should be added to the list of approved ICR programs.

We are requesting public comments on this proposed determination pursuant to section 1862(1) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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## Proposed Decision Memo

TO: Administrative File CAG-00418N

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SUBJECT: Proposed Coverage Decision Memorandum for Intensive Cardiac Rehabilitation (ICR) Program – Pritikin Program (CAG-00418N)

DATE: May 14, 2010

## I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The Pritikin Program meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c) and, as such, should be added to the list of approved ICR programs.

We are requesting public comments on this proposed determination pursuant to section 1862(1) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

## II. Background

Cardiac rehabilitation (CR) was developed in the 1950s from the concept of early mobilization after acute myocardial infarction (Pashkow, 1993). The standard of care prior to the widespread adoption of CR was bedrest and inactivity after acute myocardial infarction (Forman, et al., 2000). In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone (Ades et al., 2000). Foreman et al. (2000) states that "over subsequent years, CR broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure and stress reductions, smoking cessation, diet change, and weight loss were coupled to goals of exercise training."

The Pritikin diet was designed and adopted by Nathan Pritikin in 1955 after being "told by his cardiologist that he was at great risk of death from myocardial infarction" (Martin, 1991). The diet was modeled after the diet of the Tarahumara Indians in Mexico, which consisted of 10% fat, 13% protein, 75-80% carbohydrates and provided 15-20 grams per day of crude fiber with only 75 mg/day of cholesterol (Pritikin, 1982). With his lifestyle modifications, Pritikin reduced his serum cholesterol from 280 mg/dl to 122 mg/dl within 3 years. At autopsy in 1985, "there were no raised plaques and no compromise of the lumens" of the coronary arteries and it was noted that "In a 69 year old man, the near absence of atherosclerosis and the complete absence of its effects are remarkable" (Hubbard et al., 1985). Over the years, the Pritikin program (also known as the Pritikin Longevity Program) evolved into a comprehensive program that is provided in a physician’s office and incorporates a specific diet (10%–15% of calories from fat, 15%–20% from protein, 65%–75% from complex carbohydrates), exercise and counseling lasting 21-26 days. An optional residential component is also available for participants.

Although Medicare has covered CR for certain patients since 1982, a new part B benefit was established for ICR in §1861(eee)(4)(A) effective for items or services furnished on or after January 1, 2010.

## III. Statutory and Regulatory Background

The objective of this national coverage analysis is to determine if the Pritikin program meets the new statutory and regulatory requirements to be approved as a Medicare ICR program. Medicare internally generated this analysis in order to determine whether the Pritikin program meets the ICR program requirements and would be eligible for Medicare coverage.

Intensive cardiac rehabilitation (ICR) refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the Social Security Act, an ICR program must show, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcomes. To implement this provision, CMS added 42 C.F.R. §410.49. This section was added through rulemaking in the CY 2010 Physician Fee Schedule Final Rule. See 74 Fed. Reg. 61,738, 61,872 (November 25, 2009).

As required by §1861(eee)(4)(A)(i) of the Act, to be approved as a Medicare ICR program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients: (1) positively affected the progression of coronary heart disease; (2) reduced the need for coronary bypass surgery; and (3) reduced the need for percutaneous coronary interventions. As required by §1861(eee)(4)(A)(ii) of the Act, an ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications. ICR programs must be approved through the NCD process to ensure that they demonstrate these accomplishments (42 C.F.R. §410.49(c)).

Intensive cardiac rehabilitation program sessions are limited to 72 one-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks (§1861(eee)(4)(C), 42 C.F.R. §410.49(f)(2)).

**Benefit Category**

Medicare is a defined benefit program. An item or service must fall within a benefit category under Part A or Part B as a prerequisite to Medicare coverage. Congress has specifically authorized coverage of intensive cardiac rehabilitation under Part B of the Medicare program (§1861(eee)(4) of the Social Security Act). Through this NCD process, CMS will determine whether the Pritikin Program meets the ICR requirements.

## IV. Timeline of Recent Activities

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|---|---|
| November 17, 2009 | Internally generated NCA. Initial 30-day public comment period begins. |
| December 17, 2009 | Initial 30-day public comment period ends. |

## V. FDA

The Pritikin program is not subject to FDA oversight.

## VI. General Methodological Principles

When making national coverage determinations concerning ICR programs, CMS evaluates peer-reviewed published research to determine whether or not the ICR program meets the criteria required in §1861(eee) of the Act.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

## VII. Evidence

### A. Introduction

In this analysis, we evaluated the impact of the Pritikin program on the following health outcomes, as listed in §1861(eee): (1) the progression of coronary heart disease; (2) reduction in the need for coronary bypass surgery; and (3) reduction in the need for percutaneous coronary interventions. We also evaluated the effect of ICR on the following cardiac risk factors: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

### Literature Search

CMS evaluated peer-reviewed published research including clinical research studies, technology assessments, guidelines and reviews that focused on heart disease and were published from January, 1980 to January, 2010. General keywords included cardiac rehabilitation, exercise, and the Pritikin program. Abstracts without a complete publication were excluded. Using these general parameters, six original studies and one systematic review were found.

**B. Discussion of evidence reviewed**

1. Evidence Question

For this analysis, we focused on the following question:

Does the Pritikin Program (also known as the Pritikin Longevity Program) meet the requirements set forth in §1861(eee)(4) for an intensive cardiac rehabilitation program:

(1) positively affected the progression of coronary heart disease;
(2) reduced the need for coronary bypass surgery; and
(3) reduced the need for percutaneous coronary interventions?

As required by §1861(eee)(4)(A)(ii) of the Act, an ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

2. External Technology Assessment

*Roberts CK, Barnard RJ. Effects of exercise and diet on chronic disease. J Appl Physiol 2005;98:3–30.*

Roberts and Barnard reported the results of a systematic review to: "1) discuss the effects of exercise and diet in the prevention of chronic disease, 2) highlight the effects of lifestyle modification for both mitigating disease progression and reversing existing disease, and 3) suggest potential mechanisms for beneficial effects." The review focused on lifestyle modification programs that included physical activity and dietary interventions. Search and inclusion criteria were not reported. For coronary heart disease, the authors summarized: "Physical inactivity and dietary factors both contribute vitally to atherosclerosis and consequent CAD (coronary artery disease). Studies indicate that inactivity may be as predictive of CAD risk as conventional risk factors, exercise training may improve endothelial function[*] and is superior to percutaneous angioplasty for short-term survival. Additionally, several dietary factors such as fiber, fat (amount and type), glycemic load, and fruit and vegetable consumption appear to significantly modulate CAD risk. Combined exercise and diet interventions mitigate atherosclerosis progression and may in fact induce plaque regression and/or improve myocardial flow reserve. These benefits are, at least in part, due to reductions in plasma lipids, lipid oxidation, and inflammation. Improvements in risk factors with diet may, in some instances, be as great as with statin therapy, and lifestyle interventions combined with statin therapy possess additive effects on lipid lowering. Moreover, although obesity contributes to CAD, risk can be modified independent of large changes in weight."

Specifically for studies based on the Pritikin program, they reported: "One intervention that has been studied extensively is the Pritikin residential lifestyle intervention, designed to achieve changes in lifestyle that are very extensive in each subject. Participants undergo a complete medical history and physical examination, before a 26-day (more recently 21-day or 11-day) physical activity and diet intervention. Meals are served buffet style, and all participants are allowed unrestricted eating except for the meals when 3½ oz. of fish or fowl are provided. Prepared meals contain 10–15% of calories from fat, 15–20% of calories from protein, and 65–75% of calories from carbohydrates, primarily unrefined, according to analysis by computer dietary analysis software. Carbohydrates are in the form of high-fiber whole grains (≥ 5 servings/day), vegetables (≥ 4 servings/day), and fruits (≥ 3 servings/day). Protein is primarily derived from plant sources with small amounts of nonfat dairy (up to 2 servings/day) and fish or chicken. The diet contains < 100 mg of cholesterol, and alcohol, tobacco, and caffeinated beverages are not served during the program. Before starting the exercise training, subjects undergo a graded treadmill stress test according to a modified Bruce protocol to determine the appropriate individual level of exercise intensity. On the basis of the results, the subjects are provided with an appropriate training heart rate value and given an individualized aerobic exercise program. The exercise regimen consists of daily treadmill walking at the training heart rate for 45–60 min. The training heart rate is defined as 70–85% of the maximal heart rate attained during the treadmill test. Additionally, the subjects perform flexibility and resistance exercise. Early studies documented that this combined physical activity and diet intervention decreased all serum lipids and angina in patients, the majority of whom had a prior myocardial infarction and/or multiple vessel disease and all of whom had been recommended for bypass surgery. The majority were taken off cardiac and/or blood pressure-lowering drug therapy. The durability of the changes was evidenced by a 5-yr follow-up, which documented that adherence to the program resulted in maintenance of the changes and dramatically reduced the need for bypass surgery. The 4,587 men and women who completed the 26-day physical activity and diet intervention from 1977 to 1988 revealed an average Total-C reduction of 23%, from 234 to 180 mg/dl. LDL-C decreased by 23%, from 151 to 116 mg/dl, with male subjects exhibiting a greater reduction in Total-C (24 vs. 21%) and LDL-C (25 vs. 19%) compared with female subjects. HDL-C was reduced by 16%, but the ratio of Total-C to HDL-C was reduced by 11%. Serum TG decreased 33%, from 200 to 135 mg/dl, with male subjects showing a greater reduction than female subjects (38% vs. 23%)."

3. Internal Technology Assessment

*Barnard RJ, DiLauro SC, Inkeles SB. Effects of Intensive Diet and Exercise Intervention in Patients Taking Cholesterol-Lowering Drugs. Am J Cardiol 1997;79:1112-1114.*

Using a case series/quasiexperimental study design, Barnard and colleagues evaluated serum lipid changes in a group of 93 participants in the Pritikin Longevity Center 1- to 3-week program. The group ranged in age from 39-81 years, with mean age of 63, and all participants were taking cholesterol-lowering drugs at baseline. Individuals enrolled in either a 1-week or 3-week program length. Components of the program included medically supervised daily aerobic exercise (duration not specified in article), the Pritikin diet (same as described above in 2002 study by Roberts, et al.), twice per week progress evaluations by physicians, and daily educational lectures (mainly concerning diet/exercise). The authors utilized analysis of variance and paired/unpaired t-tests to assess the effect of the program on serum lipids.

Results were reported for the total group and stratified according to primary/secondary prevention. All changes in pre- vs. post-intervention lipid values were significant at $p < 0.01$. Looking at the total group: LDL cholesterol improved from 126 mg/dl before intervention, to 101 afterwards, $p < 0.01$; triglycerides improved from 195 pre- to 139 postintervention; total cholesterol and HDL cholesterol also improved "significantly." The authors also report that the percent change in total cholesterol, when comparing pre- to postintervention values, was greater in the primary prevention program than in the secondary prevention program.

The authors stated that "the results from the present study show that an aggressive diet and exercise program when added to cholesterol-lowering drugs can result in dramatic reduction in total and LDL cholesterol as well as in triglycerides."

*Barnard RJ, Guzy PM, Rosenberg JM, and Trexler O'Brien L. Effects of an intensive exercise and nutrition program on patients with coronary artery disease: five-year follow up. J Cardiopulm Rehabil 3:183-190, 1983.*

Barnard and colleagues reported the results of an observational study of 64 patients "to evaluate the progress of a group of patients with documented CAD who participated in a residential program during the years 1976-77." The 26 day Pritikin program was used and comprised of a high carbohydrate, high fiber, low fat diet (less than 10% of calories from fat, 13% from protein, remainder from carbohydrate; 10 to 20 grams of fiber; < 25 mg of cholesterol; and 4 grams of sodium), exercise, and health education. All patients had coronary artery disease documented by angiography and were recommended for bypass surgery by their personal physicians. Exclusion criteria were not reported. Outcomes included serum lipid levels, dietary compliance, exercise, body weight, blood pressure, medication status, mortality and bypass surgery. Analysis of variance significance testing was used. Mean age was 57 years. Men comprised 89% of the study population.

The authors reported significant reductions in serum cholesterol, triglycerides, systolic and diastolic blood pressure, regular exercise, body weight, and medications. At the 5 year follow-up, there were 4 (6%) deaths and 12 (19%) patients had received bypass surgery. The authors noted that the mortality rate at the time for patients with documented CAD was "as high as 50% by the third year." They stated: "In conclusion, the results obtained from this small group of high-risk patients with documented CAD indicate that a high-complex-carbohydrate, high-fiber, low-fat, low-cholesterol diet combined with regular exercise and smoking cessation is a very effective adjunct program for secondary prevention in patients with coronary heart disease."

*Barnard RJ,, Ugianskis EJ, Martin DA, Inkeles SB. Role of diet and exercise in the management of hyperinsulinemia and associated atherosclerotic risk factors.* Am J Cardiol 1992;69:440-444.

Barnard and colleagues reported the results of a case series of 72 patients to evaluate whether "lifestyle modification including a low-fat, high-complex-carbohydrate diet combined with daily aerobic exercise can be effective for controlling hyperinsulinemia and the related atherosclerotic risk factors." Patients with diabetes, insulin resistance, and normal insulin were included. The intervention consisted of the 26 day Pritikin Program diet and exercise. The diet was the Pritikin Eating Plan ("Of the total calories, < 10% were derived from fat (polyunsaturated/saturated = 1.24), 10 to 15% from protein, and 75 to 80% from carbohydrate. Protein was derived from other than animal sources, with the exception of nonfat milk served daily and small amounts of fish or fowl served twice weekly, not > 100 g/week. Carbohydrates were supplied in the form of vegetables, fruits, legumes and whole grains. Thirty-five to 40 g of dietary fiber per 1,000 kcal were provided each day. The diet contained < 25 mg of cholesterol and 4 g of sodium chloride per day. Alcohol, tobacco and caffeinated beverages were not permitted during the program. Food was provided ad lib"). The exercise program consisted of "walking for a minimum of 30 minutes at their training heart rate 4 to 5 times per week, and once or twice a week upwards of 45 minutes below their training heart rate." Outcomes included serum insulin, serum lipids, blood pressure, BMI, and medication status. Mean age was 57 years. Men comprised 56% of the study population.

The authors reported significant reductions in total cholesterol, low density lipoproteins, trigylcerides, body mass index, systolic blood pressure, diastolic blood pressure and the use of antihypertensive medications. As with all case series, there was no control group. Long term outcomes were not reported.

*Roberts CK,Vaziri ND, Barnard RJ. Effect of Diet and Exercise Intervention on Blood Pressure, Insulin,Oxidative Stress, and Nitric Oxide Availability. Circulation 2002; 106:2530-2532.*

This case series/quasi-experimental study evaluated outcomes due to participation in the diet and exercise intervention offered at the Pritikin Longevity Center. Serum was collected from 11 men, age range 38-72 (mean age not stated) who voluntarily participated in the Pritikin Longevity Center 21-day diet and exercise intervention. Most participants were obese, and many had a baseline diagnosis of either diabetes and/or metabolic syndrome. Outcomes were compared between preintervention and postintervention. The diet component of the program consisted of prepared meals with specific nutrient composition: approx. 10% of calories from fat, 15-20% from proteins, 70-75% from mainly unrefined carbohydrates, and high fiber (> 40 grams/day). No restriction on quantity of food eaten was specified. The exercise component of the program consisted of daily walking at the "training heart rate" for 45-60 minutes.

Using matched pair t-tests to compare pre- and postintervention values, Pritikin and colleagues observed significant improvements in the following parameters: BMI (37.6 ± 2.8 pre-intervention, to 36.1 ± 2.6 postintervention, $p < 0.01$); LDL-C (113.2 ± 6.1 pre-intervention to 87.5 ± 6.0 postintervention, $p < 0.01$); triglycerides (223 ± 52 pre- to 131 ± 20 postintervention, $p < 0.05$); systolic BP (137.8 ± 4.3 pre- to 119.0 ± 2.9 postintervention, $p < 0.01$); diastolic BP (81.4 ± 2.2 pre- to 73.4 ± 2.4, $p < 0.01$). Significant results were also noted for total cholesterol, ratio of total cholesterol to HDL, insulin levels (significance of $p < 0.05$ or better for these parameters) and also for improvements in two markers of inflammation and/or oxidative stress (and potentially for CVD): 8-iso-PGF2a ($p < 0.05$) and urinary NOx ($p < 0.05$).

The authors conclude that "the present study is the first to show that unrestricted consumption of a low-fat, high-fiber diet and daily exercise can mitigate oxidative stress, improve NO availability, and normalize BP in obese men within 3 weeks." Weight loss was not found to be a significant contributor in this study, "as there was no association between changes in BP and BMI." In addition, the reduction of 8-iso-PGF2a (an oxidative stress marker) seen in this study "suggests amelioration of oxidative stress by the diet and exercise intervention," which (e.g. via inc. NO) may lead to decreased risk of hypertension.

*Roberts CK, Won D, Pruthi S, Kurtovic S. Effect of a short-term diet and exercise intervention on oxidative stress, inflammation, MMP-9, and monocyte chemotactic activity in men with metabolic syndrome factors. J App. Physiol 2006;100:1657-1665.*

Roberts and colleagues used a case series/quasi-experimental design to examine the effects of lifestyle modification on several contributing factors to atherogenesis, including oxidative stress and inflammation, while also measuring changes in lipids, glucose, insulin and BMI, pre/post-intervention. Serum samples were taken from 31 overweight/obese middle-aged and older men (mean age 63, mean BMI 33) who all voluntarily participated in the Pritikin Longevity Center 21-day diet and exercise intervention in 2001. At baseline, 15 of the 31 participants had metabolic syndrome according to World Health Organization modified criteria, and thirteen people had Type 2 diabetes. The intervention was the same as the one described above in the 2002 study by Roberts et al. Each participant had a graded treadmill stress test to determine appropriate individual level of exercise intensity, and associated goal training heart rate. To compare preintervention with postintervention blood measurements, the authors used matched-pair t-tests. Also, Pearson's correlation coefficients were determined for comparing relationships between the inflammatory measures, such as CRP, with cardiovascular risk markers such as BMI and glucose.

In looking at post-intervention changes in CV risk factors, the authors noted significant improvements in the following parameters: BMI (35.4 pre-intervention to 34.4 postintervention, $p < 0.01$); LDL-C (calculated, 118.1 mg/dL preintervention to 88.1 post, $p < 0.01$); triglycerides (215.0 mg/dL preintervention to 156.4 post, $p < 0.01$; insulin (30.9 microU/mL preintervention to 21.6 post, $p < 0.01$); blood glucose (125.9 mg/dL preintervention to 110.3 post, $p < 0.01$). Other changes noted by the authors included significant improvement in oxidative stress (e.g. serum MPO, or myeloperoxidase, $p < 0.05$), as well as significant changes in inflammatory proteins, including CRP (C-reactive protein, $p < 0.01$), ICAM-1 ($p < 0.05$), sP-selectin ($p < 0.01$) and MMP-9 (index of plaque stability, $p < 0.01$).

In conclusion, the authors state that the findings indicate that, in men with metabolic syndrome, "lifestyle [including implementation of a high-fiber, low-fat diet, combined with daily aerobic exercise] may 1) improve the lipid and metabolic profile, 2) decrease oxidative stress and increase NO production, 3) decrease inflammation, 4) decrease endothelial cell activation, 5) decrease monocyte adhesion and MCA, 6) decrease MMP-9, a marker of plaque destabilization."

*Sullivan S, Klein S. Effect of short-term Pritikin Diet therapy on the metabolic syndrome.* J Cardiometabolic Syndrome 2006;Fall:308-312.

Sullivan and Klein reported the results of a case series of 67 patients to evaluate the effect of the Pritikin program on the metabolic risk factors for coronary heart disease. All patients had metabolic syndrome and attended the Pritikin Program for 12 to 15 days. Metabolic syndrome was defined as having ≥ 3 criteria as defined by the National Cholesterol Education Program (NCEP) guidelines. The intervention consisted of a comprehensive diet and exercise. "The diet consisted of 10%–15% of calories from fat, 15%–20% from protein (primarily from plants but also from seafood, fowl, or bison), and 65%–75% from carbohydrate (comprising whole grains, vegetables, and fruits), and contained about 40 g/1000 kcal of fiber. Salt was limited to < 1500 mg/d and cholesterol to < 100 mg/d. Alcohol, tobacco products, and caffeinated beverages were not allowed." Exercise was individually tailored and consisted of outdoor walking and daily exercise for a "total of 45–60 minutes of aerobic exercise performed to achieve a heart rate of 70%–85% of maximal heart rate." Of the 67 patients, 40 had diabetes and 51 were taking medications. Primary outcomes included blood pressure, BMI, serum glucose and serum lipids. Mean age was 60 years. Men comprised 78% of the study population.

The authors reported "body mass index decreased by 3% (P < .001); systolic and diastolic blood pressure, and serum glucose and low-density lipoprotein cholesterol concentrations decreased by 10%–15% (P < .001); serum triglyceride concentration decreased by 36% (P < .001); and 37% of subjects no longer met National Cholesterol Education Program criteria for the metabolic syndrome." They concluded: "These data demonstrate that brief treatment with a very-low-fat, low-sodium, high-fiber diet and regular exercise simultaneously improves multiple CHD risk factors in patients with the metabolic syndrome." As with all case series, there was no control group. Long term outcomes were not reported.

4. MEDCAC

No Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) was convened for this issue.

5. Evidence-based guidelines

No evidence based guidelines specific to the Pritikin Program were found.

6. Professional Society Position Statements

No professional society position statements specific to the Pritikin program have been released.

7. Public Comments

Public comment sometimes cites the published clinical evidence and gives CMS useful information. The CMS uses the initial public comments to inform its proposed decision. The CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. During the initial 30-day public comment period CMS received six comments. Four comments are supportive of coverage for the Pritikin Program, one comment is not supportive of coverage and one comment was outside the scope of this NCD.

## VIII. CMS Analysis

This national coverage determination (NCD) is a scope of benefit determination and is made by the Secretary with respect to whether or not a particular ICR program meets the benefit category coverage requirements under title XVIII of the Social Security Act, §1861(eee)(4). Congress specifically authorized coverage of ICR if certain criteria are met as described in Section III of this document.

For this analysis, we addressed the following question:

Does the Pritikin Program (also known as the Pritikin Longevity Program) meet the requirements set forth in §1861(eee)(4) for an intensive cardiac rehabilitation program:

(1) positively affected the progression of coronary heart disease;
(2) reduced the need for coronary bypass surgery; and
(3) reduced the need for percutaneous coronary interventions?

As required by §1861(eee)(4)(A)(ii) of the Act, an ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.

*Progression of coronary heart disease, reduction in the need for coronary bypass surgery, reduction in the need for percutaneous coronary interventions.*

The study by Barnard and colleagues (1983) showed that participation in the Pritikin program was associated with a reduction in the need for bypass surgery. Although the sample size was small, the study provided long term follow-up. At five years, there were four deaths (6%). There was no direct comparison group but the authors reported that, at the time (1976-1977), mortality associated with coronary artery disease was "as high as 50% by the third year." At five years 12 patients (19%) had bypass surgery. Since al1 patients were recommended to have bypass surgery prior to enrollment, there was a reduction in bypass surgery over the follow-up period.

*Statistically significant reduction in 5 or more of the following measures: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and (6) the need for cholesterol, blood pressure, and diabetes medications.*

The study by Sullivan and colleagues (2006) and the studies by Roberts and colleagues (2002, 2006) showed that participation in the Pritikin Program led to significant reductions in low density lipoprotein, triglycerides, body mass index, systolic blood pressure, and diastolic blood pressure. The studies by Barnard and colleagues (1992, 1997) showed that participation in the Pritikin Program led to significant reductions in low density lipoprotein, triglycerides, body mass index, systolic blood pressure, diastolic blood pressure, and medication use. Considered together, these published studies provided evidence that participation in the Pritikin program led to significant reductions in these cardiac risk factors.

Based upon evidence published in the medical literature, the Pritikin Program meets the requirements set forth in §1861(eee)(4) for an intensive cardiac rehabilitation program.

## IX. Conclusion

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The Pritikin Program meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in our regulations at 42 C.F.R. §410.49(c)and, as such, should be added to the list of approved ICR programs.

We are requesting public comments on this proposed determination pursuant to section 1862(1) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum. [*] Function of the endothelium, a thin membrane that lines the inner surface of blood vessels.

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Roberts CK, Won D, Pruthi S, Kurtovic S. Effect of a short-term diet and exercise intervention on oxidative stress, inflammation, MMP-9, and monocyte chemotactic activity in men with metabolic syndrome factors. J Appl. Physiol 2006; 100:1657-1665.

Sullivan S, Klein S. Effect of short-term Pritikin Diet therapy on the metabolic syndrome. J Cardiometabolic Syndrome 2006;fall:308-312. *

* Denotes citations referenced by public commenters. CMS reviews all public commenters' citations and includes relevant articles in the evidence review.
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